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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,493	01/24/2002	Francois Hirsch	P67289US0	6661

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EXAMINER
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SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/926,493	<b>Applicant(s)</b> HIRSCH ET AL.	
	<b>Examiner</b> Richard Schnizer, Ph. D	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 64-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 64-126 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims embrace a wide variety of conjugates having various specific structural characteristics, wherein the conjugates do not form a single general inventive concept under PCT Rule 13.1. For example:

Independent claim 64 is drawn to a conjugate for transferring a nucleic acid molecule into a cell, wherein the conjugate must have a nucleic acid molecule, a translocation domain, and an antibody specific for a surface antigen of said cell, wherein these three elements are conjugated by means of at least one bridging agent such that the conjugate is transfected effectively into said cell.

Independent claim 77 is drawn to a conjugate for transferring a nucleic acid molecule into a cell, wherein the conjugate must have a nucleic acid molecule, an antibody specific for a cell surface antigen, and a nucleic acid binding molecule, such that the conjugate is transfected effectively into said cell.

Independent claim 83 is drawn to a conjugate for transferring a nucleic acid molecule into a cell, wherein the conjugate must have a nucleic acid molecule, an antibody specific for a cell surface antigen, and a peptide that can be cleaved with at least one glycolytic and/or proteolytic enzyme, such that the conjugate is transfected effectively into said cell.

Dependent claims specify various structural features such as peptide linkers, particular chemical bridging groups, and various arrangements specifying which functional element is linked to which.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The technical feature linking the independent claims is a conjugate for transferring a nucleic acid to a cell, wherein the conjugate must have a nucleic acid, and an antibody specific for a surface antigen of said cell. It is evident from the international preliminary examination report that the technical feature linking the independent claims is not novel, and none of the independent claims is novel.

For example, WO 96/13599 describes a nucleic acid transfer system, including a translocation domain, for targeting a nucleic acid to a specific cell. The system comprises a multidomain protein including a nucleic acid binding domain (see page 6), target cell-specific ligand such as an antibody (see pages 7 and 8), and a translocation domain (see pages 5 and 10). The nucleic acid may be single or double stranded RNA or DNA, and may encode a protein (see page 11). So, WO 96/13599 anticipates independent claims 64 and 77, as well as the technical feature linking the 3 independent claims.

WO 94/13325 discloses a conjugate containing polylysine covalently modified with avidin, a biotinylated monoclonal antibody bound to the avidin, and a plasmid DNA complexed with the polylysine. So, WO 94/13325 anticipates independent claim 77, as well as the technical feature linking the 3 independent claims.

Also Chakrabarti et al (1996) taught a conjugate comprising an oligonucleotide bound to a peptide cleavable by a proteolytic enzyme, which is covalently bound to a specific cell targeting antibody. So, Chakrabarti anticipates independent claim 83, as well as the technical feature linking the 3 independent claims.

As discussed further in the international preliminary examination report, the dependent claims that are not anticipated by the cited art differ from that art by the nature of the bond between the various functional domains of the conjugates, but these linkages and the use of various bridging agents was well known to those of ordinary skill in the art prior to the invention, as was the use of cleavable peptide linkers. As a result none of the claims was considered to be inventive.

Because the species are not linked by a special technical feature, Applicant must elect a single conjugate for examination on the merits. More specifically, Applicant must specify whether or not the conjugate comprises a peptide that can be cleaved with at least one glycolytic and/or proteolytic enzyme, and if so, to what elements of the conjugate it is bound, and by what bridging agent it is bound; Applicant must specify

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whether or not the conjugate comprises a translocation domain, and if so, to what elements of the conjugate it is bound, and by what bridging agent it is bound; and Applicant must specify whether or not the conjugate comprises a nucleic acid binding molecule, and if so, what it is (i.e. poly L lysine, poly D lysine, polyethylenimine, polyamidoamine, histones, protamine, ornithine, putrescine, spermidine, spermine, transcription factors, or homeobox proteins), to what it is bound, and by what bridging agent it is bound.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the

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hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in black ink, appearing to read 'Richard Schnizer', with a horizontal line extending to the right.

Richard Schnizer, Ph.D.  
Primary Examiner  
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